

REMARKS

Reconsideration is requested.

Return of an initialed copy of the attached PTO 1449 Form is requested as acknowledgement of consideration of the attached listed references. The attached PTO 1449 Form further lists pending applications and granted U.S. patent known by the undersigned to claim benefit of the same U.S. provisional applications as the cited WO03/017992. The Examiner is requested to consider the applications and file histories, which are believed to be available to the Examiner without requiring the separate submission of the same, relating to U.S. Serial Nos. 10/225,437, 10/225,460 and 10/225,461. The Examiner is requested to confirm consideration of the same in the Examiner's next Action.

Claims 1-11 and 23-26 have been canceled, without prejudice. Claims 12-22, 27 and 28 are pending. Claims 27 and 28 find support, for example, in claim 15. No new matter has been added.

The above amendments make moot the following rejections:

the Section 101 rejection of claims 1-11;

the Section 112, second paragraph, rejection of claims 1-11; and

the Section 102 rejection of claims 23 and 25 over Raad (U.S. Patent No. 5,688,516). Withdrawal of the rejections is requested.

The Section 102 rejection of claims 1-26 over Petyaev (WO 03/017992), is traversed. The rejection is moot with regard to claims 1-11 and 23-26, which have been canceled above. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

Independent claim 12 provides a method for treating a disorder of lipid metabolism comprising administering an anti-microbial agent and a metal chelator to an individual in need thereof.

Petyaev (W003/017992) discloses the treatment of atherosclerotic conditions through the inhibition of anti-Chlamydia abzymes. Azithromycin and aspirin are two examples of abzyme inhibitors which are proposed for use either individually or in combination to treat atherosclerotic conditions

The presently claimed invention relates to the treatment of disorders of lipid metabolism using combinations of metal chelators and anti-microbial compounds. These combinations are shown in the specification to alter lipid metabolism in individuals, for example by reducing levels of total cholesterol and ApoB.

The cited art is not believed to teach each and every aspect of the claimed invention and withdrawal of the Section 102 rejection is therefore requested.

The present specification describes the treatment of individuals in need of treatment which is different from Petyaev. The treatment of disorders of lipid metabolism as described in the present specification and presently claimed are not inherently described in the methods of Petyaev, which relate to the treatment of atherosclerotic conditions.

The presently claimed invention requires administration of a combination of anti microbial compound and metal chelator to an individual with a recognized need to treat a disorder of lipid metabolism.

This Examiner is requested to consider the following comments from Jansen v. Rexall Sundown, Inc., 68 USPQ2d 1154, 1158 (Fed. Cir. 2003), in this regard:

In both Rapoport and this case, the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone "in need." In both cases, the claims' recitation of a patient or a human "in need" gives life and meaning to the preambles' statement of purpose. See *Kropa v. Robie*, 187 F.2d 150, 152 [88 USPQ 478] (CCPA 1951) (stating the rule that a preamble is treated as a limitation if it gives "life and meaning" to the claim). The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed. We need not decide whether we would reach the same conclusion if either of the "treating or preventing" phrase or the "to a human in need thereof" phrase was not a part of the claim; together, however, they compel the claim construction arrived at by both the district court and this court.

The applicant believes that there is no disclosure in Petyaev et al of the treatment of an individual with a recognized need to treat a disorder of lipid metabolism with a combination of an anti-microbial compound and metal chelator. The instant claims are therefore patentable over Petyaev et al and withdrawal of the Section 102 rejection over the same is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required to place the application in condition for allowance.

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Amendment

Respectfully submitted,

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